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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,666	04/19/2006	John Michael Corbett	2913474-003000	7937

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EXAMINER

YU, MELANIE J

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1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,666	Applicant(s) CORBETT ET AL.	
	Examiner MELANIE YU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 21, 22 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20, 23, 24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II, claims 16-27, in the reply filed on 5 December 2008 is acknowledged. Applicant also elects the following species: group B-up to 500 rpm from species and group C-an intercalating dye. The species group B restriction has been withdrawn and the rotor speeds are rejoined and will be examined.

Claims 1-15, 21, 22 and 25 are withdrawn as being drawn to a non-elected invention.

Claim Objections

2. Claim 19 is objected to because of the following informalities: the word "carded" appears to be a typographical error and should be changed to --carried--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 16-18, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner et al. (US 2002/0168652).

Werner et al. teach a method of measuring the binding of a first partner in an interaction to a second partner in an interaction, wherein the interaction partners are molecular entities, the method comprising the steps of:

delivering a quantity of the second interaction partner to a reaction well of a device (disc has flow channels, which are reaction wells, par. 13) for attachment of the second interaction partner to an attachment zone of the reaction well (DNA capture probes are bound to the surface of the disc and are therefore delivered to the reaction well, par. 13; capture DNA attached to a layer in the target zone, par. 55);

adding a solution comprising a quantity of the first interaction partner to the attachment zone (test sample is injected into the flow channel, and contacted with the capture DNA, par. 84) and incubating at a temperature for a time sufficient to allowing binding of the first interaction partner to the second interaction partner (par. 137);

rotating the device rotor at a speed sufficient to displace the solution comprising unbound first interaction partner from the attachment zone (after hybridization, disc is rotated to clear the target zones of unattached sample and labels, par. 84); and

measuring the amount of the first interaction partner bound to the second interaction partner via fluorescence of an indicator molecule bound thereto (par. 62).

With respect to claim 17, Werner et al. teach the first and second interaction partners being a nucleic acid and a nucleic acid (analytes are DNA and capture molecules are DNA, par. 50 and 53).

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Regarding claim 18, Werner et al. teach the first interaction partner delivered as a solution containing a buffer (par. 117) and the second interaction partner delivered as a solution containing a hybridization buffer (par. 125).

With respect to claim 20, Werner et al. teach carrying out the displacement step at a speed of 2000 rpm and 5000 rpm (par. 140), which is encompassed by the recited greater than 500 rpm.

Regarding claim 23, Werner et al. teach the indicator molecule being a cyanine dye, which is an intercalating dye (par. 62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652).

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Werner et al. teach carrying out the step of adding a solution comprising a quantity of the first interaction partner with the rotor rotating (par. 83), but do not teach the specific rpm of the rotating rotor. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claims 19 are for any particular purpose or solve any stated problem, and the prior art teaches that the rpm may be varied to assist with mixing (par. 83). Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the biodisc art.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652), as applied to claims 16 and 23, in view of Gjerde et al. (US 6,210,885).

Werner et al. teach the indicator molecule being an intercalating dye of cyanine, but fail to teach the dye being Sybr green.

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Gjerde et al. teach a DNA binding dye of either cyanine or Sybr green (col. 8, line 53-col. 9, line 8), in order to provide detection of a DNA complex that is reversibly labeled.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the dye of Werner et al., Sybr green as taught by Gjerde et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected signal would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Gordon et al. (US 2002/0098528).

Werner et al. teach measuring fluorescence, but fail to teach the measuring step while the rotor is rotating at a speed of at least 500 rpm.

Gordon et al. teach moving an incident beam for detection in a detection chamber by rotating a biodisc about an axis (par. 19), in order to provide perpendicular scanning of the detection chamber.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Werner et al., rotating the biodisc as taught by Gordon et al., in order to provide fast detection of bound analyte.

Although Werner et al. in view of Gordon et al. do not specifically teach the rotating speed being at least 500 rpm. However, it has long been settled to be no more

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than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claim 26 are for any particular purpose or solve any stated problem, and the prior art teaches that the rotating speed may be varied in order to control the speed of detection. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the biodisc art.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Almogy (US 6,236,454).

Werner et al. teach at least one reaction well having multiple attachment zones and measurement of the amount of the interaction partner bound to the second interaction partner via the fluorescence of an indicator molecule (148, Fig. 3; par. 12 and 67), but fail to teach detection using multiple detectors.

Almogy teaches detection of fluorescence in multiple regions (spots) using multiple photodetectors (multiple spots and one photodetector per spot, col. 2, line 56-

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col. 3, line 5), in order to resolve sufficiently small pixels by having the ability to place detectors at non-oblique angles.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Werner et al., multiple photodetectors with one photodetector per detection region as taught by Almogy, in order to increase the detection rate of a detection system.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641